

(7) § 312.6.

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PART 630—GENERAL REQUIREMENTS FOR BLOOD, BLOOD COMPONENTS, AND BLOOD DERIVATIVES

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 355, 360, 371; 42 U.S.C. 216, 262, 264.

SOURCE: 66 FR 31176, June 11, 2001, unless otherwise noted.

§ 630.6 Donor notification.

(a) *Notification of donors.* You, an establishment that collects blood or blood components, must make reasonable attempts to notify any donor, including an autologous donor, who has been deferred based on the results of tests for evidence of infection with a communicable disease agent(s) as required by § 610.41 of this chapter; or who has been determined not to be suitable as a donor based on suitability criteria under § 640.3 or § 640.63 of this chapter. You must attempt to obtain the results of supplemental testing required under § 610.40(e) of this chapter prior to notifying a donor of the deferral. If notification occurs prior to receipt of such results, you must also notify a deferred donor of the results of the supplemental testing. You must notify a donor as described in paragraph (b) of this section.

(b) *Content of notification.* You must provide the following information to a donor deferred or determined not to be suitable as a donor as described in paragraph (a) of this section:

(1) That the donor is deferred or determined not to be suitable for donation and the reason for that decision;

(2) Where appropriate, the types of donation of blood or blood components that the donor should not donate in the future;

(3) Where applicable, the results of tests for evidence of infection due to communicable disease agent(s) that were a basis for deferral under § 610.41 of this chapter, including results of supplemental (i.e., additional, more specific) tests as required in § 610.40(e) of this chapter; and,

(4) Where appropriate, information concerning medical followup and counseling.

(c) *Time period for notification.* You must make reasonable attempts to notify the donor within 8 weeks after determining that the donor is deferred or determined not to be suitable for donation as described in paragraph (a) of this section. You must document that you have successfully notified the donor or when you are unsuccessful that you have made reasonable attempts to notify the donor.

(d) *Autologous donors.* (1) You also must provide the following information to the referring physician of an autologous donor who is deferred based on the results of tests for evidence of infection with a communicable disease agent(s) as described in paragraph (a) of this section:

(i) Information that the autologous donor is deferred based on the results of tests for evidence of infection due to communicable disease agent(s), as required under § 610.41 of this chapter, and the reason for that decision;

(ii) Where appropriate, the types of donation of blood or blood components that the autologous donor should not donate in the future; and

(iii) The results of tests for evidence of infection due to communicable disease agent(s), that were a basis for deferral under § 610.41 of this chapter, including results of supplemental (i.e., additional, more specific) tests as required in § 610.40(e) of this chapter.

(2) You must make reasonable attempts to notify the autologous donor's referring physician within 8 weeks after determining that the autologous donor is deferred as described in paragraph (a) of this section. You must document that you have successfully notified the autologous donor's referring physician or when you are unsuccessful that you have made reasonable attempts to notify the physician.

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

Subpart A—Whole Blood

- Sec.
640.1 Whole Blood.
640.2 General requirements.
640.3 Suitability of donor.
640.4 Collection of the blood.
640.5 Testing the blood.
640.6 Modifications of Whole Blood.

Subpart B—Red Blood Cells

- 640.10 Red Blood Cells.
640.11 General requirements.
640.12 Suitability of donor.
640.13 Collection of the blood.
640.14 Testing the blood.
640.15 Segments for testing.
640.16 Processing.
640.17 Modifications for specific products.

Subpart C—Platelets

- 640.20 Platelets.
640.21 Suitability of donors.
640.22 Collection of source material.
640.23 Testing the blood.
640.24 Processing.
640.25 General requirements.
640.27 Emergency provisions.

Subpart D—Plasma

- 640.30 Plasma.
640.31 Suitability of donors.
640.32 Collection of source material.
640.33 Testing the blood.
640.34 Processing.

Subpart E [Reserved]

Subpart F—Cryoprecipitate

- 640.50 Cryoprecipitate AHF.
640.51 Suitability of donors.
640.52 Collection of source material.
640.53 Testing the blood.
640.54 Processing.
640.55 U.S. Standard preparation.
640.56 Quality control test for potency.

Subpart G—Source Plasma

- 640.60 Source Plasma.
640.61 Informed consent.
640.62 Medical supervision.
640.63 Suitability of donor.
640.64 Collection of blood for Source Plasma.
640.65 Plasmapheresis.
640.66 Immunization of donors.
640.67 Laboratory tests.
640.68 Processing.

- 640.69 General requirements.
640.70 Labeling.
640.71 Manufacturing responsibility.
640.72 Records.
640.73 Reporting of fatal donor reactions.
640.74 Modification of Source Plasma.
640.76 Products stored or shipped at unacceptable temperatures.

Subpart H—Albumin (Human)

- 640.80 Albumin (Human).
640.81 Processing.
640.82 Tests on final product.
640.83 General requirements.
640.84 Labeling.

Subpart I—Plasma Protein Fraction (Human)

- 640.90 Plasma Protein Fraction (Human).
640.91 Processing.
640.92 Tests on final product.
640.93 General requirements.
640.94 Labeling.

Subpart J—Immune Globulin (Human)

- 640.100 Immune Globulin (Human).
640.101 General requirements.
640.102 Manufacture of Immune Globulin (Human).
640.103 The final product.
640.104 Potency.

Subpart K [Reserved]

Subpart L—Alternative Procedures

- 640.120 Alternative procedures.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

SOURCE: 38 FR 32089, Nov. 20, 1973, unless otherwise noted.

CROSS REFERENCES: For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21–12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see parts 124 and 125 of the Domestic Mail Manual, that is incorporated by reference in 39 CFR part 111.

Subpart A—Whole Blood

§ 640.1 Whole Blood.

The proper name of this product shall be Whole Blood. Whole Blood is defined as blood collected from human donors for transfusion to human recipients.

[38 FR 32089, Nov. 20, 1973, as amended at 50 FR 4138, Jan. 29, 1985]